C. REMARKS

In the Office Action of 3 August 2006, claims 10, 11, 14-16, 24, 25, 28, and 29 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,464,391 to *Devale*; claims 10, 13-17, 21-24, 28, and 29 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,462,256 to *Minick*; claims 10, 11, 14-16, 21-25, 28, and 29 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,158,437 to *Natwick*; and claims 12, 19, 20, 26, and 27 were rejected under 35 U.S.C. § 103 as being obvious in view of U.S. Patent No. 5,158,437 to *Natwick*, U.S. Patent No. 5,462,256 to *Minick* or U.S. Patent No. 5,464,391 to *Devale* in view of U.S. Patent No. 5,647,852 to *Atkinson* and U.S. Patent No. 4,665,943 to *Medvick.*

In response, claims 10, 16, 17, 21, 22, 23, 24, and 28 have been amended to clarify the invention while claims 14, 15, and 29 have been cancelled.

The present invention provides a removable pump cassette for use with a surgical irrigation pump having a pumping actuator. The pump cartridge defines a pumping chamber in fluid communication with a source of fluid and an irrigation conduit. In one embodiment, the pumping chamber is defined in part by the diaphragm, with the diaphragm positioned to cooperate with a reciprocating pumping actuator and the diaphragm being preloaded against the reciprocating pumping actuator. The cartridge is removably connected to the surgical irrigation pump to establish working communication with the pumping actuator. In one embodiment, the cartridge is removably connected to the surgical irrigation pump by a tab-receiving groove in the cartridge cassette which is adapted to mate with a laterally outwardly projecting tab on the surgical irrigation pump to provide coupling of the cartridge cassette in the surgical irrigation pump. An upstream valve is disposed in the cartridge and is in fluid communication with the source of fluid and the pumping chamber. A downstream valve is disposed in the cartridge and is in fluid communication with the irrigation conduit and the pumping chamber.

Claim 10 has been amended to specify that the pumping chamber is defined in part by the diaphragm, that the diaphragm is positioned to cooperate with a reciprocating pumping actuator, and that the diaphragm is preloaded against the reciprocating pumping

actuator. Claim 24 has been amended to specify the diaphragm has a consistent graduated cross-sectional thickness dimension such that the thickness dimension is composed of a constant graduated increase from a central portion of the diaphragm to radially outward portions of the diaphragm.

U.S. Patent No. 5,464,391 to *Devale* describes an irrigation system and method for providing fluid from a source of irrigating fluid to a minimally invasive surgical site. The irrigation system includes a control unit that is used with a cassette. The cassette includes a fluid flow passageway having an inlet connected to the source of irrigating fluid and an outlet for providing fluid to the surgical site. A pump located in the cassette is driven by the motor.

Initially, in contrast to the cassette of the present invention, the cassette of *Devale* is used with a rotary-type pump and not a reciprocating pump as in the present invention. Thus, the cassette of *Devale* includes an impeller 70 that is driven by an output shaft 48 of a motor 39. In contrast to the allegation in the Office Action, as a rotary-type pump the inlet 28 and the outlet 34 of *Devale* do not include valves.

In addition, while *Devale* does include a flexible membrane 88, this flexible membrane is used to sense pressure and ***not*** to cooperate with a reciprocating pumping actuator. The Office Action refers to "Col 5 line 25" in arguing that the membrane is preloaded. In fact, there is no such teaching of preloading, and, again, this is a pressure sensing membrane:

> "The second sensor 54, which is used to measure pressure, is located so that it corresponds to the location of the pressure sensing area 78. A portion of the wall of the housing 59 in the pressure sensing area 78 is formed of a flexible membrane 88. In a preferred embodiment, the flexible membrane is made of silicon rubber. In a preferred embodiment, the flexible membrane 88 located across an aperture 90 through a wall of the cassette housing 59."

Column 5, lines 20-29.

It is respectfully not understood how the depiction of the pressure sensing membrane of *Devale* in Figure 6 shows a graduated cross-sectional thickness dimension. Clarification is requested.

U.S. Patent No. 5,462,256 to *Minick* describes a push button flow stop mounted on a disposable infusion pumping cassette provided for use with a drug infusion pump. The flow stop

is operative to enable or to block fluid flow through the cassette in a first mode and to monitor fluid pressure in the cassette in a second mode.

While the Office Action argues that the cassette of *Minick* includes a "tab receiving recess (#71, Col 4 Line 28)", this is not the case. The "notches 71" of *Minick* in fact receive "snaps" not "tabs:

> "The cassette 10, when installed in the pump housing 70, is held in place as by snaps 71a which engage the notches 71 in the side walls of the base member 14 to retain the cassette in the pump 69."

Column 6, lines 46-49.

Further, the Office Action points to "Col 4 line 17" in arguing that the diaphragm is preloaded. In fact, all that *Minick* teaches is that the diaphragm is shaped the same as the "face elliptic member 43"; nothing is said about preloading:

> "Elastomeric member 16 is a molded flexible elastomeric member also somewhat elliptic in configuration, which conforms generally to the shape of the face elliptic member 43 at the underside of upper face 38 of face member 12."

Finally, while *Minick* does have a series of ridges, it does not teach the presently claimed constantly graduated increasing thickness dimension.

Next, U.S. Patent No. 5,158,437 to *Natwick* describes a volumetric pump for use with a cassette. Inlet and outlet cracking valves are defined in respect to the forces applied by actuators against a flexible membrane in the cassette. A plunger displaces fluid from a pumping chamber in the cassette. A volumetric pump applies appropriate forces to an inlet valve actuator and an outlet valve actuator to achieve cracking and closure forces.

The Office Action points to "Col 21 line 8" in arguing that the diaphragm is preloaded. A review of this citation reveals no such teaching:

> "In FIG. 17, a cross-sectional plan view showing the fluid passages behind flexible membrane 340 illustrates the fluid flow path through cassette 300. Fluid entering inlet port 306 flows through an inlet passage 342 and through an entry port 344 at the bottom center of a proximal pressure chamber 346. Proximal pressure chamber 346 is, of course, disposed behind flexible membrane 340 in the area defined by proximal pressure sensor port 324. A sealing ridge 348 defines the perimeter of proximal pressure chamber 346 and each of the other chambers and passages within cassette 300. Flexible membrane 340 is trapped between the top of

sealing ridge 348 and the back surface of front panel 304, forming a seal that prevents fluid leakage from these chambers and passages."

Column 21, lines 1-15.

In addition, the Office Action points to "Fig 18,19, Col 21 lines 21-28" in arguing that the thickness of the diaphragm increases. In fact, the cited language is discussing the ridges that isolate the cracking channel, not the diaphragm:

> "A connecting passage 350 leads from proximal pressure chamber 346 into an outer channel 352, which is disposed behind inlet valve port 320. An inner ridge 354 separates outer channel 352 from a cracking chamber 356 that is disposed in the center of inlet valve port 320. As shown in FIGS. 18 and 19, inner ridge 354 is slightly lower in elevation than sealing ridge 348 and includes a nib 378 centered on its top surface. Sealing ridge 348 connects to inner ridge 354 and extends in an incline down to the lower elevational level of inner ridge 354 at the opening to a connecting passage 358. Connecting passage 358 leads into a pumping chamber 360, disposed behind plunger port 330."

Column 21, lines 16-28. In addition, it is respectfully not understood how the depiction of the diaphragm of *Natwick* in Figures 18 and 19 shows a graduated cross-sectional thickness dimension. Clarification is requested.

Therefore, it is respectfully submitted that all of the claims recite patentable subject matter and are in condition for allowance. Accordingly, favorable reconsideration and allowance of the application is respectfully requested.

The Commissioner is authorized to charge any deficiency in fees or credit any

overpayment to Deposit Account No. 50-0256. A duplicate copy of this correspondence is enclosed for such purpose.

Respectfully submitted,

Date _____ By _____

Paul E. Schaafsma
Attorney for Applicant
Registration No. 32,664
312.664.0906 phone
312.664.0963 facsimile